SCHEDULING STATUS: **S2**

PROPRIETARY NAME (and dosage form):

Bisolvon® 0,2 %

Solution

COMPOSITION:

The solution contains bromhexine hydrochloride 10 mg per 5 ml.
Preservative: methylparaben 0,1 % *m/v*.
Other excipients: purified water, tartaric acid.
Sugar free.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION:

Bromhexine is a synthetic derivative of the herbal active ingredient vasicine.
Preclinically, it has been shown to increase the proportion of serous alveolar secretion.
Bromhexine reduces mucus viscosity and activates the ciliated epithelium (mucociliary clearance).

INDICATIONS:

Symptomatic relief of cough, associated with non-purulent excessive sputum production.

CONTRA-INDICATIONS:

Hypersensitivity to bromhexine hydrochloride or the excipients of the formulation.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Oral*:*
Adults and children over 10 years: 5 - 10 ml three times a day.
Children under 10 years: 2,5 - 5 ml three times a day.

Inhalation from a respirator:
Adults: 4 ml twice a day.
Children over 12 years: 2 ml twice a day.
Children 6 -12 years: 1 ml twice a day.
Children 2 - 6 years: 10 drops twice a day.
Children under 2 years: 5 drops twice a day.

Warming the solution prevents the possible occurrence of an initial irritating cough. If the preparation is used in the presence of bronchospasm, a bronchodilator should first be administered.
The solution may be diluted 1:1 with physiological saline solution. In order to avoid precipitation the solution should be inhaled immediately after mixing.
Note: Patients being treated with BISOLVON should be notified of an expected increase in the flow of secretions.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects:
Frequency classes: Very common (> 1/10); common (> 1/100, < 1/10); uncommon (> 1/1000, < 1/100); rare (> 1/10 000, < 1/1000); very rare (< 1/10 000).

Gastrointestinal disorders:
Common: Gastrointestinal side effects (including, for example, heartburn, stomach disorders, loss of appetite, nausea, vomiting and/or diarrhoea).

Endocrine disorders:
A transient rise in serum aminotransferase values has been reported.

Nervous system disorders:
Less frequent: Headache, dizziness and sweating.

Skin and subcutaneous tissue disorders:
Rare: Skin rashes, angio-oedema and urticaria.

Respiratory, thoracic and mediastinal disorders:
Rare: Bronchospasm.
Inhalation of BISOLVON has occasionally produced cough or bronchospasm in susceptible subjects.

Immune system disorders:
Rare: Allergic reactions, anaphylaxis.

Special Precautions:
Use with care in patients with a history of peptic ulceration as BISOLVON may disrupt the gastric mucosal barrier. Care is also advisable in asthmatic patients. Clearance of BISOLVON or its metabolites may be reduced in patients with severe hepatic or renal impairment.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See **SIDE EFFECTS AND SPECIAL PRECAUTIONS**.
Treatment is symptomatic and supportive.

IDENTIFICATION:
A clear, colourless liquid with a slightly bitter taste.

PRESENTATION:
50 ml solution contained in amber-coloured glass bottles.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Keep out of reach of children.

REGISTRATION NUMBER:
G642 (Act 101/1965).

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
sanofi-aventis south africa (pty) ltd
2 Bond Street,
1685, Midrand, SA

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
07 December 2006

BOTSWANA Reg. No.: B9304975	S3
NAMIBIA Reg. No.: 14/10.1/0198	NS1

SKEDULERINGSTATUS: **S2**

EIENDOMSNAAM (en doseervorm):

Bisolvon® 0,2 %

Sanofi Logo

Oplossing

SAMESTELLING:
Die oplossing bevat 10 mg broomheksienhidrochloried per 5 ml.
Preserveermiddel: metielparabeen 0,1 % *m/v*.
Ander bestanddele: gesuiwerde water en wynsteensuur.
Suikervry.

FARMAKOLOGIESE KLASSIFIKASIE:
A 10.1 Antitussiewe middels en ekspektorante.

FARMAKOLOGIESE WERKING:
Broomheksien is ’n sintetiese derivaat van die aktiewe bestanddeel vasisien in kruie. Preklinies is dit aangetoon dat dit die sereuse alveolêre sekresie verhoog. Broomheksien verlaag die viskositeit van die slym en aktiveer die silière epiteel (mukosiliêre suiwering).

INDIKASIES:
Simptomatiese verligting van hoes, geassosieer met ’n oormatige, nie-purulente sputumproduksie.

KONTRA-INDIKASIES:
Hipersensitiwiteit teen broomheksienhidrochloried of ander komponente van die formulasie.

SWANGERSKAP EN LAKTASIE:
Die veiligheid daarvan in swangerskap en laktasie is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Mondeliks:
Volwassenes en kinders ouer as 10 jaar: 5 tot 10 ml driemaal per dag
Kinders jonger as 10 jaar: 2,5 tot 5 ml driemaal per dag.

Inaseming deur ’n respirator:
Volwassenes: 4 ml tweemaal per dag.
Kinders ouer as 12 jaar: 2 ml tweemaal per dag.
Kinders 6 tot 12 jaar: 1 ml tweemaal per dag.
Kinders 2 tot 6 jaar: 10 druppels tweemaal per dag.
Kinders jonger as 2 jaar: 5 druppels tweemaal per dag.

Verhitting van die oplossing voorkom die moontlike voorkoms van ’n aanvanklike irriterende hoes. Indien die preparaat in die teenwoordigheid van brongospasma gebruik word, behoort ’n brongodilator eers toegedien te word. Die oplossing mag 1:1 met ’n fisiologiese soutoplossing verdun word. Om presipitasie van die middel te voorkom moet dit onmiddellik na vermenging ingeasem word.
Let wel: Pasiënte wat behandeling met BISOLVON ontvang behoort ingelig te word om ’n verhoogde vloei van sekresies te verwag.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte:

Voorkoms klassifikasie: baie algemeen (>1/10); dikwels (>1/100, <1/10); minder dikwels (>1/1000, <1/100); seldsaam (>1/10 000, <1/1000); baie seldsaam (<1/10 000)

Gastroïntestinale afwykings:
Dikwels: Gastroïntestinale newe-effekte (wat insluit bv. sooibrand, maagaandoenings, verlies aan eetlus, naarheid, braking en/of diaree).

Endokriene afwykings:
'n Verbygaande verhoging van serum aminotransferase waardes is aangemeld.

Senuweestelsel afwykings:
Minder dikwels: Hoofpyn, duiseligheid en sweet.

Vel- en subkutaneuse afwykings:
Seldsaam: Veluitslae, angioëdeem en urtikarie.

Respiratoriese-, Borskas- en Mediastinale afwykings:
Seldsaam: Brongospasma.
Inhalasie van BISOLVON het af en toe gelei tot hoes of brongospasma in vatbare pasiënte.

Immuunsisteem afwykings:
Seldsaam: Allergiese reaksies, anafilakse.

Spesiale voorsorgmaatreëls:
Gebruik met sorg in pasiënte met 'n geskiedenis van peptiese ulserasie aangesien BISOLVON die slymvliesskans van die maag mag verbrokkel. Sorg word ook in asmatiese pasiënte aanbeveel. Die suiwering van BISOLVON of sy metaboliete mag vertraag wees in pasiënte met ernstige verswakte hepatiese of renale funksie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Sien **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS**.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
'n Helder, kleurlose vloeistof met 'n effens bitter smaak.

AANBIEDING:
Bruingekleurde bottels met 50 ml oplossing.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 25 °C. Hou buite bereik van kinders.

REGISTRASIENOMMER:
G642 (Wet 101/1965).

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
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